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December 30, 2013

VIA e-mail to medicalmarijuana@health.nv.gov

Marla McDade-Williams
Department of Health and Human Services
4150 Technology Way, Suite 300
Carson City, Nevada 89706

Re: Further Public Comment on Draft Regulations Promulgated Pursuant to SB 374

Dear Ms. McDade-Williams:

We write to provide you with our further public comments on the draft regulations, and in follow up to the hearings in which we participated on December 23, 2013. We request that our prior suggestions be further evaluated in light of these regulations, to which we add the following comments:

We begin by returning to the concept, which we have previously urged, of a single source pilot program in order to produce the highest quality medicine with the least risk of diversion. We again make this request, and reiterate some language we believe is useful in advancing those goals.

Nevada has the opportunity to mandate the production of the first pharmaceutical grade cannabis, make that production sustainable, and develop systems and methods that minimize diversion. No such program exists, anywhere. Nevada can create a pilot program to pioneer this approach. Nevada needs a pilot program to determine how to cultivate and process medical cannabis safely and sustainably, and perhaps even determine what really constitutes medical cannabis. Cannabis cultivated for the medical market in other states is often predicated on illicit marijuana strains and cultivation methods that produce high-THC marijuana preferred by recreational users rather than the non-psychoactive aspects that are more medicinal in nature. The focus on THC ensures diversion and export into interstate illicit markets, diversion that plagues medical marijuana programs in California and Colorado. Nevada can avoid this pitfall.

The overwhelming majority of cannabis research in the past decade focuses on the medical benefits of cannabis beyond THC. Cannabis constituents such as CBD, THCV, CBG, CBDV, and essential oils called terpenes, are of great medicinal value. Yet, the optimization of cultivation techniques to produce other constituents is not well understood. Nevada needs a pilot medical cannabis cultivation that pioneers production of medical cannabis beyond THC content. A pilot program that leverages scientific and medical expertise from UN-Reno, UNLV and the Nevada medical community, instead of repurposing ideas from underground marijuana cultivation.

Medical cannabis cultivation must be environmentally sustainable. But indoor marijuana cultivation has a huge carbon footprint in electricity and air conditioning. Indoor cultivation cited in a recent Rand study, consumes 1% the country's electricity. Nevada's climate provides greater challenges to sustainable cannabis cultivation. The solution is controlled environment cannabis production that eliminates the high intensity electric lighting used in illicit marijuana cultivation. No state, including Arizona, has recognized that sustainable cultivation is a necessity in the desert. Nevada needs a pilot program to develop sustainable approaches to cannabis cultivation.

Medical cannabis cultivation demands significant water resources. In Nevada's high desert, sustainable water management is critical. Cannabis cultivation consumes 28 acre-inches of water per year, compared with the 10 acre-inches required by corn. A pilot program for medical cannabis that develops sustainable water reclamation and recycling is imperative.

Neither the upcoming American Herbal Pharmacopeia monograph on Cannabis nor the American Herbal Products Association guidelines for medical cannabis cultivation provide tested advice on the proper cultivation and processing of medical cannabis, and often stress the problems. The AHP monograph indicates that the bacterial and mold content of Dutch medical cannabis cultivation distributed throughout the European Community is so high that the cannabis must be irradiated with gamma rays to kill bacteria and mold, to reach the levels safe for human consumption under the European Pharmacopeia guidelines. A pilot program that develops techniques to produce cannabis with safe microbial levels is imperative to ensure patient safety.

Additionally, the upcoming AHP monograph on Cannabis recommends testing methods for cannabis that require additional controlled substances to perform accurate testing of cannabinoid content. These controlled substances include diazepam (Valium) and the anabolic steroid, androstenedione. By using controlled substances in the testing methods, the monograph introduces a Catch-22. This is not usable guidance makes testing at an accredited lab study at a Nevada university impossible. DEA will not license any medical cannabis entity beyond their federal program at the University of Mississippi, so academic institutions and mainstream analytical laboratories in Nevada run the risk of losing DEA licenses allowing them to research and analyze any controlled substance, if they accept any medical cannabis product for analysis or study from a source not explicitly approved by DEA. Nevada needs a pilot program that develops validated laboratory methods that do not rely on controlled substances for calibration.

Accordingly, as to Section 132, we propose the following amendment: *132. Pursuant to the authority granted by SB 374 and these regulations, the Division shall establish an 18 month pilot program wherein a single Registration for a Cultivation Facility will be granted to the Applicant who receives the highest score pursuant to the Division's Merit Based Permit Application Process (MBPAP), that can demonstrate that it can safely meet the anticipated consumption by those persons with valid Registry Identification Cards who have designated a Medical Cannabis Dispensary, and that can demonstrate established procedures and resources that address the eight points of concern stated in the August 29, 2013, memorandum published by Deputy United States Attorney James Cole. Following the expiration of this pilot program, the Division may issue additional Cultivation Facility Registrations if the Division determines that the Pilot Program Registrant is unable to meet statewide need. The Division shall ensure that the number of additional Cultivation Facility Registrations that it approves, if any, is not more than the minimum number of facilities necessary to meet the needs of Nevada's medical cannabis patient population and the non-resident populations of medical cannabis consumers based on figures developed during the period of the pilot program. In any event, such registrations shall not exceed the Divisions's ability to enforce the provisions of SB 374, these regulations, or the points of concern raised by the Cole Memo, particularly with respect to ensuring patient safety and preventing illegal diversion of cannabis. The Cultivation Facility selected for participation in the Pilot Program established by the State of Nevada under these regulations shall have, as part of its security plan, [1] the use of federally deputized, armed security personnel who patrol the outside perimeter of the facility, stand at checkpoints located at each place of ingress and egress to the facility, patrol the interior of the facility and who are authorized to search outgoing packages to confirm that cannabis is not being diverted to unlawful uses; and [2] the identification and retention of a state-approved security consultant who shall have ongoing responsibilities to monitor the facility's security operations and implement alterations thereto as circumstances warrant*

Other suggested amendments are as follows:

Section 26(12)(a): Amend to read as follows: The likely impact of the proposed medical marijuana establishment in the community in which it is proposed to be located, *including whether said establishment intends to recognize, its employee's rights to collectively bargain through card check neutrality, or has done so by either by recognizing a labor association as a bargaining agent or entering into a CBA with such labor association.*

Section 35(1)(a): Amend to read as follows: Before an additional person or persons gain an aggregate ownership interest *greater than 5%* in the medical marijuana establishment, *unless such additional interests are approved by the Division pursuant to the application process outlined in these regulations.*

Section 41: Amend to add new subsection 8, as follows: 8. *The educational requirements set forth in this regulation may be conclusively deemed to have been satisfied by completion of a training course accredited by the Division.*

Section 55(2): Add new subsection (d), as follows: (d) *This section shall not apply to licensed consultants who perform professional services not involving the physical handling or transportation of marijuana, including, without limitation, attorneys, accountants, security officers, medical doctors, experts in the treatment of conditions using marijuana.*

Section 57(3)(d)(9)(III): Strike this subsection.

Section 67: Add new subsections 4-6, as follows:

4. Medical Marijuana Establishments that function as dispensaries must comply with applicant requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPPA). Such MMEs must maintain the confidentiality of patient records and may only disclose such information pursuant to a patient authorization or lawful administrative or court process. Such MMEs must have HIPPA-compliant policies and providing patients the following notices of those policies:

- 1. Notice of Privacy Practices and Privacy Policies;*
- 2. Notice of Authorized, Non-Authorized, Restriction of Use, and Disclosure Policies;*
- 3. Notice of Medical Record Amendment Policy;*
- 4. Notice of Privacy Complaint Policy;*
- 5. Confidentiality and Confidential Communications Policies; and*
- 6. Patient Access to Medical Record Policy.*

5. Nothing in this regulation shall be deemed to authorize disclosure of any patient's medical record, or of any specific medical condition of a particular patient.

- 6. 1. Except as otherwise provided in this section and NRS 239.0115, the Division and any designee of the Division shall maintain the confidentiality of and shall not disclose the name or any other identifying information of any person who is registered with the State or with any MME registrant as a Qualified Patient or Primary Caregiver. Except as otherwise provided in NRS 239.0115, the name and any other identifying information of any such person is confidential, not subject to subpoena or discovery and not subject to inspection by the general public.*
- 2. Notwithstanding the provisions of subsection 1, the Division or its designee may release the name and other identifying information of a person who Qualified Patient or Primary Caregiver pursuant to chapter 453A of NRS or this chapter to:*
 - (a) Authorized employees of the Division or its designee as necessary to perform official duties of the Division; and*
 - (b) Authorized employees of state and local law enforcement agencies, only as necessary to verify that person's lawfully status as a Qualified Patient or Primary Caregiver*

Add new Section 72A, as follows: 72A. *In addition to the requirements set forth in Sections 10-10.5 of SB 374, a Cultivation Facility seeking an initial Registration must submit information as to its practices, procedures and requirements in the following particulars:*

- 1. Research: A Cultivation Facility must provide a plan by which it intends to either conduct its own ongoing research or collect and analyze the research of third parties, as to the effect of medical cannabis on the medical conditions for which its use is authorized under state law, develop strains of medical cannabis that reduce the adverse effects profile of high-THC medical cannabis, develop strains of medical cannabis that contain appreciable amounts of CBDA, CBGA, THCVa, and CBDVa and other cannabinoids with reduced psychoactivity;*

2. Education: A Cultivation Facility must provide a plan by which it intends to educate its own MME Agents and staff, the MME Agents and staff of the other MMEs to which it supplies its product, and the public, as to the effects of medical cannabis on the medical conditions for which its use is authorized under state law and the most appropriate, least burdensome methods for consuming such cannabis for each such condition.
3. Testing: A Cultivation Facility must identify the procedures and methods by which it will have the cannabis it produces tested, both for the items required under these regulations and any other item or component that is helpful to the ultimate consumer in making an informed decision concerning the type of cannabis to be consumed and the most appropriate method of consumption. A Cultivation Facility may conduct in house/on-site testing, including state-mandated tests, with validation of the state mandated tests by an independent laboratory registered with the state to conduct such testing;
4. Security: A Cultivation Facility must identify the procedures and methods by which it will secure its premises in order to protect against theft, diversion and other inventory losses, and in particular to address the concerns stated in the August 29, 2013, Cole Memo. Such plans shall include the identification and retention of a state-approved security consultant who shall have ongoing responsibilities to monitor the facility's security operations and implement alterations thereto as circumstances warrant.
5. Resource conservation: A Cultivation Facility must identify the procedures and methods by which it will conserve and reclaim water – potable or otherwise -- used in all of its cultivation and industrial processes, as well as a plan by which its carbon footprint relating to the use of electricity and/or natural gas will be significantly reduced.

Section 81: Amend to add new subsection 4, as follows: 4. *The educational requirements set forth in this regulation may be conclusively deemed to have been satisfied by completion of a training course accredited by the Division.*

Regarding Sections 118-121, add the following provisions in lieu of the proposed testing regime:

- *For cannabis that is ultimately intended for human consumption in any form, including Usable Cannabis (whether it be for direct consumption or via an extract, infused, or edible product), the Cultivation Facility must conduct a foreign matter inspection, moisture content analysis, potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), terpene analysis, including for myrcene, beta-caryophyllene, limonene, linalool, terpinolene, alpha-pinene, beta-pinene, and ocimene (expressed in mg/g), pathogenic molds, aflatoxins, microbial contaminants screen including but not limited to e coli, and salmonella (expressed in CFU/g), heavy metals (expressed in mcg/g), and synthetic plant growth regulators, chemical additives and pesticides (including insecticides, herbicides and fungicides), listed by the Cultivation Facility as being used in the cultivation process (expressed in either ppm or mcg/g). In addition to such tests, Usable Cannabis shall also be tested for five (5) random, commonly used synthetic plant growth regulators, chemical additives and pesticides (including insecticides, herbicides and fungicides) that were not listed by the Cultivation Facility as being used in the cultivation process (expressed in either ppm or mcg/g);*
- *For extract of cannabis (non-solvent based), such as kief, hashish, bubble hash, infused dairy butter or oil/fats derived from natural sources, which must be produced from previously tested Cannabis, the Production Facility must re-test for foreign matter inspection, potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), pathogenic molds and microbial contaminants including but not limited to e coli, and salmonella (expressed in CFU/g);*
- *For cannabis to be used to make an extract of cannabis (solvent based) made with a C02 extractor, or with food grade ethanol or glycerin, which must be produced from previously tested Cannabis, the Production Facility must re-test for foreign matter inspection, potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), pathogenic molds and microbial contaminants including but not limited to e coli, and salmonella (expressed in CFU/g) and residual C02, ethanol or glycerin (expressed in ml);*

- *For extract of cannabis (solvent based), which is produced using n-butane, isobutane, propane, heptane or other solvents or gases approved by the Division of at least 99% purity, and which must be derived from previously tested cannabis, the Production Facility must re-test for potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), residual solvent used in the process (expressed in ml) and, as to cannabis that failed the initial pathogenic molds or microbial contaminants test, re-test as to such contaminants, including but not limited to e coli, and salmonella (expressed in CFU/g);*
- *For extract of cannabis, which is produced with a C02 extractor, such as hash oil, and which must be derived from previously tested cannabis, the Production Facility must re-test for potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), residual C02 (expressed in mcg/g), and, as to cannabis that failed the initial pathogenic molds or microbial contaminants test, re-test as to such contaminants, including but not limited to e coli, and salmonella (expressed in CFU/g);*
- *For extract of cannabis, which is produced with food grade ethanol, and which must be derived from previously tested cannabis, the Production Facility must re-test for potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), residual ethanol (in ml), and, as to cannabis that failed the initial pathogenic molds or microbial contaminants test, re-test as to such contaminants, including but not limited to e coli, and salmonella (expressed in CFU/g);*
- *For extract of cannabis, which is produced with food grade glycerin or propylene glycol, and which must be derived from previously tested cannabis, the Production Facility must re-test for potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), residual glycerin or propylene glycol (in ml), and, as to cannabis that failed the initial pathogenic molds or microbial contaminants test, re-test as to such contaminants, including but not limited to e coli, and salmonella (expressed in CFU/g);*
- *For edible cannabis-infused products, which must be derived from previously tested cannabis, the Production Facility must re-test for foreign matter, potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), pathogenic molds and microbial contaminants, including but not limited to e coli, and salmonella (expressed in CFU/g);*
- *For liquid cannabis-infused products, which must be derived from previously tested cannabis, the Production Facility must re-test for foreign matter, potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), pathogenic molds and microbial contaminants, including but not limited to e coli, and salmonella (expressed in CFU/g);*
- *For topical cannabis-infused products, which must be derived from previously tested cannabis, the Production Facility must re-test for potency analysis (expressed in mg/g of D-9 THC, THCA, CBD, CBDA, CBG, CBGA, THCV, THCVA, CBDV, CBDVA, CBGV and CBGVA), pathogenic molds and microbial contaminants, including but not limited to e coli, and salmonella (expressed in CFU/g).*

We also propose the following language be added as a new Section 146: 146. *With respect to security and oversight procedures, including with regard to location of cameras and panic buttons, and the hiring and stationing of security personnel, such information shall be submitted under seal and not disclosed to the general public, and not subject to subpoena or discovery other than by law enforcement in furtherance of a criminal investigation.*

Very truly yours,
LAW OFFICES OF MARC L. TERBEEK

/s/

Marc L. TerBeek